

WHAT IS CLAIMED IS:

- 1                   1.       An expression vector, said vector comprising an expression cassette  
2 comprising two components:
  - 3                   (a) a eukaryotic promoter and a first RNA polymerase promoter operably  
4 linked to a nucleic acid encoding a secretable RNA polymerase having a secretion domain,  
5 and a first internal ribosome entry site (IRES); and  
6                   (b) a second RNA polymerase promoter operably linked to a nucleic acid  
7 encoding a product of interest and a second internal ribosome entry site.
- 1                   2.       The expression vector of claim 1, wherein said eukaryotic promoter is  
2 a cytomegalovirus promoter.
- 1                   3.       The expression vector of claim 1, wherein said RNA polymerase is a  
2 non-host RNA polymerase.
- 1                   4.       The expression vector of claim 1, wherein said RNA polymerase is a  
2 T7 RNA polymerase.
- 1                   5.       The expression vector of claim 1, wherein said first IRES and said  
2 second IRES are the same.
- 1                   6.       The expression vector of claim 1, wherein said first IRES and said  
2 second IRES are different.
- 1                   7.       The expression vector of claim 1, wherein said first IRES and said  
2 second IRES are from encephalomyocarditisvirus.
- 1                   8.       The expression vector of claim 1, wherein said secretion domain is a  
2 member selected from the group consisting of: SEQ ID NOS: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11,  
3 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40,  
4 41, 42, 43, 44, and 45.
- 1                   9.       The expression vector of claim 1, wherein said product of interest is a  
2 therapeutic product.

1                   10.     The expression vector of claim 9, wherein said therapeutic product is a  
2 member selected from the group consisting of: a protein, a nucleic acid, an antisense nucleic  
3 acid, ribozymes, tRNA, siRNA, and an antigen.

1                   11.     A host cell comprising the expression vector of claim 1.

1                   12.     A lipid-nucleic acid composition comprising:  
2 a nucleic acid-lipid particle comprising a lipid portion and a nucleic acid  
3 portion,  
4 wherein said nucleic acid portion comprises an expression cassette comprising  
5 two components:

6                   (a) a eukaryotic promoter and a first RNA polymerase promoter operably  
7 linked to a nucleic acid encoding a secretable RNA polymerase having a secretion domain,  
8 and a first internal ribosome entry site; and

9                   (b) a second RNA polymerase promoter operably linked to a nucleic acid  
10 encoding a product of interest and a second internal ribosome entry site.

1                   13.     The lipid-nucleic acid composition of claim 12, wherein said nucleic  
2 acid-lipid particle is a serum-stable nucleic acid-lipid particle comprising a nucleic acid fully  
3 encapsulated within said lipid portion.

1                   14.     The lipid-nucleic acid composition of claim 12, wherein said lipid  
2 portion comprises a cationic lipid, a non-cationic lipid; and a polyethyleneglycol-lipid  
3 conjugate.

1                   15.     The lipid-nucleic acid composition of claim 14, wherein said cationic  
2 lipid is a member selected from the group consisting of: N,N-dioleoyl-N,N-  
3 dimethylammonium chloride (DODAC), N,N-distearyl-N,N-dimethylammonium bromide  
4 (DDAB), N-(1-(2,3-dioleoyloxy)propyl)-N,N,N-trimethylammonium chloride (DOTAP), N-  
5 (1-(2,3-dioleoyloxy)propyl)-N,N,N-trimethylammonium chloride (DOTMA), and N,N-  
6 dimethyl-2,3-dioleoyloxy)propylamine (DODMA), and a mixture thereof.

1                   16.     The lipid-nucleic acid composition of claim 14, wherein said non-  
2 cationic lipid is a member selected from the group consisting of  
3 dioleoylphosphatidylethanolamine (DOPE), palmitoylloleoylphosphatidylcholine (POPC),

4 egg phosphatidylcholine (EPC), distearoylphosphatidylcholine (DSPC), cholesterol, and a  
5 mixture thereof.

1 17. The lipid-nucleic acid composition of claim 14, wherein said cationic  
2 lipid comprises from about 2% to about 60% of the total lipid present in said particle.

1 18. The lipid-nucleic acid composition of claim 14, wherein said non-  
2 cationic lipid comprises from about 5% to about 90% of the total lipid present in said particle.

1 19. The lipid-nucleic acid composition of claim 14, wherein said PEG-  
2 lipid conjugate comprises from 1% to about 20% of the total lipid present in said particle.

1 20. The lipid-nucleic acid composition of claim 14, wherein said non-  
2 cationic lipid is DSPC.

1 21. The lipid-nucleic acid composition of claim 14, further comprising  
2 cholesterol.

1 22. The lipid-nucleic acid composition of claim 21, wherein the cholesterol  
2 comprises from about 10% to about 60% of the total lipid present in said particle.

1 23. The lipid-nucleic acid composition of claim 14, wherein  
2 the cationic lipid comprises 7.5% of the total lipid present in said particle;  
3 the non-cationic lipid comprises 82.5% of the total lipid present in said  
4 particle; and  
5 the PEG- lipid conjugate comprises 10% of the total lipid present in said  
6 particle.

1 24. The lipid-nucleic acid composition of claim 14, wherein the nucleic  
2 acid-lipid particle comprises:  
3 DODMA;  
4 DSPC; and  
5 a PEG- lipid conjugate.

1 25. The lipid-nucleic acid composition of claim 24, further comprising  
2 cholesterol.

3                   26.     A method of expressing a nucleic acid encoding a product of interest in  
4 a cell, said method comprising:

5                   introducing into a cell an expression vector comprising an expression cassette  
6 comprising two components:

7                   (a) a eukaryotic promoter and a first RNA polymerase promoter operably  
8 linked to a nucleic acid encoding a secretable RNA polymerase having a secretion domain,  
9 and a first internal ribosome entry site; and

10                  (b) a second RNA polymerase promoter operably linked to a nucleic acid  
11 encoding a product of interest and a second internal ribosome entry site.

1                   27.     The method of claim 26, wherein said RNA polymerase is a T7 RNA  
2 polymerase.

1                   28.     The method of claim 26, wherein said secretion domain is a member  
2 selected from the group consisting of: SEQ ID NOS: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13,  
3 14, 15, 16, 17, 18, 19, 20, 21, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42,  
4 43, 44, and 45.

1                   29.     The method of claim 26, wherein said expression vector is fully  
2 encapsulated in a lipid portion of a serum stable nucleic acid-lipid particle.

1                   30.     The method of claim 26, wherein said product of interest is a  
2 therapeutic product.

1                   31.     The method of claim 26, wherein said therapeutic product is a member  
2 selected from the group consisting of: a protein, a nucleic acid, an antisense nucleic acid,  
3 ribozymes, tRNA, siRNA, and an antigen.

1                   32.     A method of delivering a nucleic acid encoding a product of interest to  
2 a cell, said method comprising:

3                   introducing into the cell an expression vector comprising an expression  
4 cassette comprising two components:

5                   (a) a eukaryotic promoter and a first RNA polymerase promoter operably  
6 linked to a nucleic acid encoding a secretable RNA polymerase having a secretion domain,  
7 and a first internal ribosome entry site; and

8 (b) a second RNA polymerase promoter operably linked to a nucleic acid  
9 encoding a product of interest and a second internal ribosome entry site.

1 33. The method of claim 32, wherein said cell is in a mammal.

1 34. The method of claim 33, wherein said mammal is a human.

1 35. A method of treating a disease in a subject, comprising:  
2 administering a therapeutically effective amount of an expression cassette  
3 comprising two components:

4 (a) a eukaryotic promoter and a first RNA polymerase promoter operably  
5 linked to a nucleic acid encoding a secretable RNA polymerase having a secretion domain,  
6 and a first internal ribosome entry site; and

7 (b) a second RNA polymerase promoter operably linked to a nucleic acid  
8 encoding a therapeutic product and a second internal ribosome entry site.

1 36. The method of claim 35, wherein said subject is a mammal.

1 37. The method of claim 36, wherein said mammal is a human.

1 38. The method of claim 35, wherein said expression vector is fully  
2 encapsulated in a lipid portion of a serum stable nucleic acid-lipid particle.

1 39. The method of claim 35, wherein said disease is a member selected  
2 from the group consisting of: a cancer, an autoimmune disease, a cardiovascular disease, a  
3 viral disease, a bacterial disease, and an inflammatory disease.

1 40. An isolated purified nucleic acid comprising the sequence set forth in  
2 SEQ ID NO: 46, 50, or 51.